

## CLAIMS

1. An expandable intra-gastric balloon (1) for treating obesity, for implanting in the stomach of a patient to reduce the volume of the stomach, said balloon (1)  
5 comprising a first flexible pouch (2) defining a predetermined inside volume, said first flexible pouch (2) being provided with first connection means (3) including an orifice (4) and a valve (5) for receiving a connection member (6) for connection to a first fluid  
10 source in order to expand said first pouch (2) in the stomach by filling it with the fluid, the balloon being characterized in that it includes at least one second flexible pouch (20) of predetermined volume and provided with second connection means (3') with an orifice (4')  
15 and a valve (5'), said second connection means (3') being separate from the first connection means (3) so as to be capable of being connected to a second fluid source different from the first fluid source.
- 20 2. A balloon according to claim 1, characterized in that said at least one second pouch (20), of volume smaller than that of the first pouch (2), is disposed inside the first pouch (2).
- 25 3. A balloon according to claim 2, characterized in that said at least one second pouch is disposed substantially concentrically with the first pouch (20).
4. A balloon according to claim 2 or claim 3,  
30 characterized in that the orifices (4, 4') are substantially in alignment, so as to be capable of receiving a common connection member (10A).
5. A balloon according to any one of claims 2 to 4,  
35 characterized in that it includes spacer means (10, 10A) for holding said at least two pouches (2, 20) respectively at a distance apart from each other.

6. A balloon according to claim 5, characterized in that the spacer means (10, 10A) are formed by spacers holding and fixing the two pouches (2, 20) at a distance from  
5 each other.

7. A balloon according to claim 6, characterized in that it includes two spacers (10, 10A) that are substantially diametrically opposite each other about the common center  
10 of the two pouches (2, 20).

8. A balloon according to claim 6 or claim 7, characterized in that the spacers (10, 10A) are formed by two base plates interconnected by a leg (11), each base  
15 plate being fixed, e.g. by adhesive, to a respective one of the first and second pouches.

9. A balloon according to any one of claims 5 to 8, characterized in that the first and second connection  
20 means (3, 3', 10A) are common to the two pouches and are formed by one of the spacers.

10. A balloon according to claim 9, characterized in that the common connection means (10A) comprises a hollow  
25 central duct (21) formed by the leg (11) of the spacer (10), said duct having two holes (22, 23), each in register with the inside volume of a respective one of the first and second pouches (2, 20), and each being associated with a respective valve (5, 5'), said duct  
30 being suitable for receiving a connection member (6) for differentially filling each of the pouches (2, 20) with a distinct filler fluid.

11. A balloon according to any one of claims 1 to 10,  
35 characterized in that the first pouch (2) is filled with a liquid, the second pouch (20) being filled with a gas.

12. A balloon according to any one of claims 1 to 11, characterized in that the outside surface of the balloon is subdivided into cells (2C).

5 13. A surgical device for treating obesity, the device serving to expand an intra-gastric balloon itself comprising a first pouch (2) and a second pouch (20) disposed inside the first pouch (2), the pouches having respective orifices (4, 4') arranged to receive a common  
10 connection member (10A) in the stomach of a patient, said device comprising a tubular connection member (6) suitable for being inserted in a hollow central duct (21) of the common connection means (10A) of the intra-gastric balloon, said member being provided with two independent  
15 channels (15, 16) each having a respective end opening out in register with a corresponding one of two holes (22, 23) in the central duct (21), and each having its opposite end connected to a respective independent endpiece (17, 18) suitable for being connected to  
20 distinct filler fluid sources.

14. A device according to claim 13, characterized in that the two channels (15, 16) are concentric.

25 15. A method of fabricating an intra-gastric balloon comprising a first pouch and a second pouch disposed inside the first pouch, the pouches having respective orifices arranged to receive a common connection member, in which method, the following steps are performed:  
30       • fabricating first and second pouches by injecting elastomer material in a mold to obtain at least two pouches each having a respective orifice, the first pouch being of dimensions greater than those of the second pouch; and  
35       • during the step of fabricating the first pouch or thereafter, placing a spacer on the outside face of the

first pouch substantially opposite from its orifice, the spacer presenting a free outer base plate; then

• bonding the two pouches together at the free outer base plate by using adhesive between said base plate and the outside face of the second pouch, substantially  
5 opposite from its orifice; and then

• turning the first pouch inside out, causing the second pouch to penetrate therein via its orifice.

10 16. A method according to claim 14, characterized by subsequently placing the common connection means of the two pouches in the two substantially aligned orifices of the first and second pouches, and bonding said common means thereto via its two base plates.

15 17. An intra-gastric balloon (1) for treating obesity, for implanting in the stomach (31) of a patient in order to reduce the volume of the stomach, said balloon (1) comprising an outside wall (2A) for coming into contact  
20 with the wall (30) of the stomach (31), the balloon (1) subdividing the stomach (31) into an upstream zone (31A) and a downstream zone (31B) in order to constitute a barrier for the passage of food between these two zones, the outside wall (2A) being shaped so to co-operate with  
25 the wall (30) of the stomach to define channels (32) for passing food from the upstream zone (31A) to the downstream zone (31B), the balloon being characterized in that the outside wall (2A) is shaped so that the channels (32) form a network branching at more than two points, so  
30 as to constitute a path of tree structure for food passing from the upstream zone (31A) to the downstream zone (31B).

18. A balloon (1) according to claim 17, characterized in  
35 that the outside wall (2A) has a plurality of projections (33) arranged relative to one another in such a manner that the channels (32) are defined firstly by the

interstices between the projections (33) and secondly by the wall (30) of the stomach (31) in contact with the tops (34) of said projections (33).

5 19. A balloon (1) according to claim 18, characterized in that each projection (33) projects from a substantially polygonal base, the polygonal bases touching one another over at least a fraction of the surface of the outside wall (2A).

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20. A balloon (1) according to claim 19, characterized in that the projections are arranged relative to one another in a truncated icosahedron pattern.

15 21. A balloon (1) according to any one of claims 17 to 20, characterized in that it is constituted by a flexible pouch that is expandable by being filled with fluid, the pouch being constituted by an envelope whose outside face forms the outside wall (2A).

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22. A balloon (1) according to claims 21 and 19 or according to claims 21 and 20, characterized in that the envelope is formed by assembling polygonal bases via their sides (32A), the core (33) of each base being more  
25 flexible than the sides (32A) of each base, such that during inflation of the pouch by being filled with fluid, the core (33) of each base deforms more than the sides (32A), thus having the effect of generating protuberances that form the projections (33).

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23. A balloon (1) according to claim 22, characterized in that the envelope is made of an elastomer material such that the core (33) of each base is of smaller thickness than the sides, thereby obtaining different flexibility  
35 between the core (33) and the sides (32A) of each base.

24. A balloon (1) according to claim 23, characterized in that the envelope is made by associating a fabric presenting a mesh forming the sides (32A) of the bases, with an elastomer film forming the core (33) of each  
5 base, the mesh being less deformable than the elastomer film.

25. An intra-gastric balloon (1) for treating obesity, for implanting in the stomach of a patient to reduce the  
10 volume of the stomach, said balloon (1) comprising a flexible envelope (2) defining a predetermined inside volume, said flexible envelope (2) being made of an elastomer material, the balloon being characterized in that the dimensional tolerance (T) on the nominal  
15 thickness ( $e_{nom}$ ) of the envelope lies in the range 1% to 20%.

26. An intra-gastric balloon (1) according to claim 25, characterized in that the tolerance (T) lies in a range  
20 10% to 16%.

27. An intra-gastric balloon according to claim 25 or claim 26, characterized in that the nominal thickness ( $e_{nom}$ ) of the envelope (2) is substantially equal to  
25 0.5 mm, with tolerance (T) lying in the range 10% to 16%.

28. An intra-gastric balloon (1) according to any one of claims 25 to 27, characterized in that the envelope (2) is made of silicone, or is based on silicone.

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29. A method of fabricating an intra-gastric balloon (1) for treating obesity, said balloon (1) being for implanting in the stomach of a patient in order to reduce the volume of the stomach, the method being characterized  
35 in that it includes an injection step in which an elastomer material is injected into a mold in order to

obtain a flexible pouch that is to form the envelope (2) on the balloon (1).

30. A method according to claim 29, characterized in  
5 that, prior to the injection step, it includes a step of  
preparing a mold in which a top cavity (40) of generally  
hemispherical shape is pressed against a bottom cavity  
(41) likewise of generally hemispherical shape, so as to  
10 obtain an inside volume that is substantially spherical  
in shape, with a spherical core (42) being previously  
positioned between the two cavities (40, 41),  
concentrically therewith, the diameter of the core being  
smaller than the diameter of said inside volume, the  
15 injection step comprising a step of injecting the  
elastomer material into the space (43) that extends  
between the core (42) and the cavities (40, 41) so as to  
obtain a pouch of generally spherical shape that is to  
form the envelope (2) of the balloon.